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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191
210	7590	05/03/2005	EXAMINER	
MERCK AND CO., INC			GIBBS, TERRA C	
P O BOX 2000			ART UNIT	
RAHWAY, NJ 07065-0907			PAPER NUMBER	
			1635	
DATE MAILED: 05/03/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,242

Applicant(s)

HASELBECK ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12, 18-20, 29-31, 37, 39, 45-96, 98-101 and 103-105 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 18-20, 29, 30, 37, 39, 70, 88, 98, 99 and 105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 31, 45-69, 71-87, 89-96, 100, 101, 103 and 104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicants Amendment and Remarks filed February 14, 2005.

Claims 12, 31, 62, 68, 77, 86-88 and 98-100 have been amended. Claims 1-9, 13-17, 21-28, 32-36, 38, 40-44, 97 and 102 have been canceled. New claims 103-105 are acknowledged. Claims 10-12, 18-20, 29-31, 37, 39, 45-96, 98-101 and 103-105 are pending in the instant application.

It is noted that in response to the restriction requirement mailed June 3, 2003, Applicants elected SEQ ID NO: 1463 as the *ypbC* antisense sequence, SEQ ID NO: 12600 as the *ypbC* polypeptide, and SEQ ID NO: 4228 as the *ypbC* nucleic acid encoding the polypeptide. Claims 10, 11, 18-20, 29, 30, 37, 39 and 70, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Further, claims 88, 98, 99 and new claim 105 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. And even further, SEQ ID NOs. 521, 1390, 1845, 2782, 3283, 5021, 5283, 10251, 10689, 10969, 11370, 11955, 13518, 13703, 3966, 6154, 6592, 6872, 7273, 7858, 8502, 9420, and 9605 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on June 30, 2002.

Claims 12, 31, 45-69, 71-87, 89-96, 100, 101, 103 and 104 have been examined on the merits to the extent they read on the elected subject matter.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

In the previous Office Action mailed November 17, 2004, the disclosure was objected to because it contains an embedded hyperlink and/or other form of browser-executable code. **This objection is withdrawn** in view of Applicants Amendment to the specification to remove embedded hyperlinks and/or other form of browser-executable codes.

Claim Rejections - 35 USC § 112

In the previous Office Action mailed November 17, 2004, claims 12, 31, 45-69, 71-87, 89-96, 100, and 101 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Further**, claims 12, 31, 45-69, 71-87, 89-96, 100, and 101 were rejected under 35 U.S.C. 112, first paragraph, because

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the specification, while being enabling for a method for screening a candidate compound for the ability to reduce cellular proliferation comprising providing a sublethal level of an antisense nucleic acid comprising SEQ ID NO: 1463, which reduces the activity of a gene product required for cellular proliferation, thereby producing a sensitized bacterial cell, does not reasonably provide enablement for a method for screening a candidate compound for the ability to reduce cellular proliferation comprising providing a sublethal level of an antisense nucleic acid comprising SEQ ID NO: 1463, which reduces the activity of a gene product required for cellular proliferation, thereby producing *any* sensitized cell, or a method for screening a candidate compound for the ability to reduce cellular proliferation comprising providing a sublethal level of an antisense nucleic acid having at least 97%, 95%, 90% 85%, 80%, 70% sequence identity to SEQ ID NO: 1463, which reduces the activity of a gene product required for cellular proliferation, thereby producing a sensitized cell. **This rejection is withdrawn** against claims 12, 85-87, 89-96 and 100 in view of Applicants Amendment filed February 14, 2005. Specifically, the Examiner has withdrawn this rejection against claims 12, 85-87, 89-96 and 100 in view of Applicants amendment to the claims to recite that the sensitized cell is a prokaryotic organism. **However, this rejection maintained** against claims 31, 45-69, 71-84 and 101 for the reasons of record set forth in the previous Office Action mailed November 17, 2004.

Response to Arguments

In response to this rejection, Applicants argue that the claims provide relevant identifying characteristics sufficient to comply with the written description requirement. For example, Applicants point the Examiner to the Guidelines at page 71435, third column, second paragraph. Applicants contend that the elected invention is directed to a method for screening a candidate compound where the target gene is one that can be inhibited using SEQ ID NO: 1463, which is an antisense oligonucleotide targeting the *S. aureus yphC* gene (SEQ ID NO: 12600). Applicants contend that the functional relationship between the target nucleic acid and antisense nucleic acid provides structural constraints and identifying characteristics. Applicants further contend that claim 31 provides various descriptions of the target gene including descriptions of genes having particular structural relationship to the target gene inhibited by SEQ ID NO: 1463. For example, Applicants argue that one of the provided relationships indicates that the target gene has at least 70% nucleic acid sequence identity to a gene that is inhibited by SEQ ID NO: 1463. Applicants contend that the reference to at least 70% nucleic sequence identity provides an identifying structural characteristic distinguishing the nucleic acid sequences from other sequences and sequence identity can be evaluated using known programs and techniques.

Applicant's arguments have been fully considered but are not found persuasive because the specification teaches SEQ ID NO: 1463, which reduces the activity of a gene product required for cellular proliferation, namely SEQ ID NO: 12600, thereby producing a sensitized bacterial cell. The issue is not that the target gene has at least

70% nucleic acid sequence identity to a gene that is inhibited by SEQ ID NO: 1463, as Applicants argue. Instead, the central issue is that there is no direction or guidance in the instant specification as filed for providing a sublethal level of an antisense nucleic acid having at least 97%, 95%, 90% 85%, 80%, 70% sequence identity to SEQ ID NO: 1463, which reduces the activity of a gene product required for cellular proliferation, thereby producing a sensitized cell. The specification as filed fails to adequately describe those antisense nucleic acids with varying degrees of sequence identity to SEQ ID NO: 1463, which produces a sensitized cell. And regarding Applicant's example, it is noted that functionality alone as recited in the instant claims does not elucidate the structure (e.g. nucleotide sequence) and it would therefore require undue experimentation to determine those antisense oligonucleotides that have at least 97%, 95%, 90% 85%, 80%, 70% sequence identity to SEQ ID NO: 1463 which reduce the activity of a gene product required for cellular proliferation, thereby producing a sensitized bacterial cell as claimed.

In summary, in view of the breadth of the claims and the lack of guidance provided by the specification, one of ordinary skill in the art at the time of the invention would have required an undue amount of experimentation to make and use the claimed invention over the scope claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 31, 45-69, 71-87, 89-96, 100, 101, 103 and 104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9 and 10 of U.S. Patent No. 6,720,139 ('139). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of screening a candidate compound for the ability to reduce the activity or level of a gene product required for cell proliferation, said method comprising the steps of: expressing an antisense nucleic acid against a nucleic acid encoding said gene product in a cell to reduce the activity or amount of said gene product in said cell, thereby producing a sensitized cell; contacting said sensitized cell with a candidate compound, wherein said candidate compound is not previously known to possess the ability to reduce cell proliferation; and determining whether said candidate compound inhibits the growth of said sensitized cell to a greater content than said candidate compound inhibits the growth of a nonsensitized cell as claimed in the issued '139 patent fully embraces the methods as instantly claimed.

Conclusion


No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wang Andrew can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
April 26, 2005


ANDREW WANG
SUPERVISORY PATENT EXAMINER
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